REMARKS

Claims 1-81 are pending in this application. By virtue of this response, claims 1-5, 9-15, 18-20, 22, 24-29, 33-38, 41-44, 46-49, 51, 54, 57, 58, 60, 62-66, 69, 70, 72-74, 77 and 81 have been amended. No new matter has been added. Amendment of certain claims is not to be construed as a dedication to the public of any of the subject matter previously presented.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is entitled "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

Restriction and Election Requirement

Applicant was previously required to make an election in response to a Restriction Requirement. Solely for the purpose of complying with 37 C.F.R. §1.143, Applicant elected the claims of Group I, with traverse. In that election, Applicant noted that each set of claims grouped by the Examiner was classified in class 607, subclass 45. To support a conclusion that a Restriction Requirement is proper, the Office Action must provide reasons and/or examples or show a "serious burden" will be placed on the Examiner, *see* MPEP §803.01. The Office Action has not complied with this requirement.

A serious burden may be shown by appropriate explanation of separate classification, separate status in the art, or a different field of search, *see* MPEP §803.01. However, as noted above, each of the claims in the application is in the **same** class and subclass and the Office Action has not explained how they have achieved a "separate status in the art." The record provides but a vague and sweeping statement that the claims "have acquired a separate status in the art because of their recognized divergent subject matter." This is inadequate to comply with the requirements set forth by the law, the rules, and the MPEP. More explanation is required. If the divergent status is indeed "recognized," then an example should be simple. In any event, it is obvious that no serious search burden is placed on the Examiner since a search has already been

performed at a level sufficient to examine and preliminarily to reject all of the "withdrawn" claims.

Similarly, Applicant was required to elect one of four species. Solely for the purpose of furthering prosecution, Applicant elected the pulse-to-pulse, pulse parameter species with traverse. The MPEP requires election of species during prosecution only when, "there is no disclosure of relationship between species," *see* MPEP §808.01(a). Applicant's specification provides sufficient disclosure of a relationship between the species. In addition, as Applicant previously noted, each of claims 1-65 is generic to the elected species since the pulse-to-pulse parameter may be varied in each invention recited by each of the Group I claims. Again, it has been made obvious that no "unduly extensive and burdensome search" was required since the search has been performed at a level appropriate to preliminarily examine and to reject the "withdrawn claims." Applicant strongly disagrees with the Restriction Requirement and the Election of Species Requirement and again requests their withdrawal.

Objection to the Drawings

Figures 1A-5A have been objected to for failing to designate a legend, such as prior art, because "only that which is old is illustrated." Applicant includes amended FIGS. 1A-5A as separate papers, which provide these designations where appropriate. The changes are shown in red for approval by the Examiner.

No new matter has been added. Applicant respectfully requests that the objection to the drawing be withdrawn. New drawings, incorporating the amendments disclosed herein will be submitted upon approval of the proposed changes.

Rejection under 35 U.S. C. §112 second paragraph

Claims 1-65

Claims 1-65 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. Applicant disagrees that the cited claims are in any respect unclear or vague. The use of active

and passive voice is permitted by the statute and by the Regulations. The brains of mammals inherently have electrical activity and that activity may be "detected" and "detectable." Further, process steps may be posited on the presence of "detected electrical activity."

Nevertheless, Applicant is acceding to the suggestion in the Office Action even though they lack support in law or in practice, in order to further prosecution of this application towards issuance. Applicant amends the claims in response to this rejection for no other reason and reserves the right to re-insert the original language into the amended claims in the event of appeal.

In particular, claim 1, was rejected for use of the term "which." Claim 1 has been amended to instead use "the." With respect to claim 3, "detected" has been changed to "detectable." Also, claim 3 has been amended to recite the phrase "electrical activity."

With respect to the rejection of claim 6 regarding use of the term "selected": such a use is part of classical Markush group terminology. Consequently, the term is proper. However, claims 9-14, 19, 22, 47, and 48 each have been amended to recite the process step in the active voice. Claim 15 has been amended to replace "electrical pulse" with "electrical burst." In claims 18, 19, 41, 42 and 49 the phrase "electrical signal" has been replaced with "electrical activity."

Claim 20 now recites a "pulse-to-pulse interval" thus providing exact correspondence for the recitation in claim 21 of "said detected epileptiform pulse-to-pulse interval." In addition, the words "again detecting" have been removed from claim 42 and claim 42 has been further amended functionally to recite the inherent result of the step and provide a correspondence used for the phrase "re-analyzed" recited in claim 43. The word "shows" has been deleted from claim 43.

Claim 46 has been amended to provide exact correspondence for the recitation in claim 49 of "electrical activity." Claims 57 and 58 have been amended to depend from claim 51, to provide antecedent basis for the phrase "a first brain electrical activity sensor." Claim 60 has been amended to delete "to said brain."

These amendments, again, are only offered to conform to the preferences found in the Office Action and not as the result of any specific part of the patent law. Withdrawal of the rejection is requested.

Claim Rejections under 35 U.S.C. §102

Claims 1-8, 12-14, 18, 19, 50-53, 57, 58, and 60

Claims 1-8, 12-14, 18, 19, 50-53, 57, 58, and 60 stand rejected under 35 U.S.C. §102(b) as being anticipated by Ward *et al.*, U.S. Patent No. 5,713,923 ("Ward"). To be anticipatory, a reference must teach each and every element of the claimed invention.

Specifically, claim 1, from which claims 2-45 depend recites, the varying of "at least one of the pulse parameters during the at least one electrical burst." Similarly, claim 50, from which claims 51-81 depend, recites pulse parameters that "vary during said burst." Ward does not show such variation. The Office Action cites Ward, column 9, lines 28-32 for the proposition that Ward discloses varying a pulse parameter during an electrical burst. However, that section states, "[e]lectrical stimulation of neural tissue may be implemented by providing pulses to electrodes **38** and **40** (FIG. 6) having amplitudes at 0.1 to 20 volts, pulse widths varying from 0.02 to 1.5 milliseconds, and repetition rates varying from 2 to 2,500 Hz."

Conspicuously absent from that quotation is the suggestion of varying any of the amplitude, pulse width, or pulse repetition rate during an electrical burst. Instead, this section merely indicates that certain stimulus parameters are variable. Once the stimulus pulse parameters are chosen, no further discussion is made of varying those parameters. Ward simply fails to teach, disclose, or even mention whether one would vary a pulse parameter during an electrical burst. Thus, the disclosure of Ward is insufficient to anticipate claim 1, and those depending from it, under 35 U.S.C. §102(b).

Furthermore, Ward does not mention or even suggest the concept of measuring electrical activity in the brain and then varying the pulse parameter during a burst, a limitation found in

many of the claims dependent on claim 1. For the foregoing reasons, Applicant respectfully submits that all pending claims are both novel and non-obvious in view of Ward.

Claims 50, 52, and 53

Claims 50, 52, and 53 stand rejected under 35 U.S.C. §102(b) as being anticipated by Weijand *et al.*, U.S. Patent No. 5,792,212 ("Weijand"). Claim 50, from which claims 52 and 53 depend, recites pulse parameters that "vary during said burst." In support of the assertion that Weijand discloses pulse parameters that vary during a burst, the Office Action notes Weijand, column 4, lines 4 and 5: "[t]hus, while the interval between successive stimulus signals varies, the window tracks this variance and thus synchronizes the sensing operation to the random timing of the delivered stimulus pulses."

However, this section does not discuss varying pulse parameters *during a burst*. Indeed, Weijand fails to even make any suggestion or show any need for varying a pulse parameter during a burst. The variance noted in Weijand is not the varying of a pulse parameter during a burst, but is instead directed toward how Weijand's "window" **45** tracks the time interval between successive stimulus signals to save energy. In this way, the window can synchronize itself to the timing of the delivered pulses and turn on energy-using circuits **43** and **46**, thus providing overall savings in energy. Applicant requests the rejection of claims 50, 52, and 53 over Weijand be withdrawn.

Allowable Subject Matter

Claim 41 has been objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant thanks Examiner for noting such allowable subject matter. However, Applicant submits that all claims are now allowable, thus obviating the need for rewriting claim 41 in independent form.

Conclusion

Applicant has responded to each matter of substance raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 459992000700. Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**".

Respectfully submitted,

Dated: October 18, 2002 By: _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Please amend the specification as follows:

Please replace the first paragraph on page 3 with:

Conventional neurostimulators use fixed rate trains of either monophasic or biphasic electrical pulses of a fixed amplitude to stimulate neural tissue [(ref?)]. Neurons in the immediate vicinity of the electrodes are induced to fire (i.e. are recruited) by the electrical pulses thereby modifying the natural electrical activity in the brain. During an epileptic event, there is abnormal synchronization of neural activity in the brain. The present invention improves upon the prior art by varying the timing, amplitude and/or duration of the pulses to more effectively disrupt the synchronized activity. Furthermore, the subject invention analyzes the effect on the brain of the electrical pulses, and decides how to modify the burst parameters in a subsequent burst to most effectively terminate the seizure.

In the Claims:

Please amend claims 1-6, 9-15, 18-20, 22, 24-29, 33-38, 41-44, 46, 47, 49, 57, 58, 60, 62-66, 69, 72-74, 77, and 81 as follows:

1. (Amended). A method for treating an abnormal neurological condition comprising the steps of :

applying to brain tissue at least one electrical burst comprising a multiplicity of pulses, said pulses having pulse parameters[,]; and

varying at least one of [which] the pulse parameters [vary] during the at least one electrical burst.

2. (Amended). The method of claim 1 wherein the step of varying at least one of the pulse parameters comprises varying at least two of said pulse parameters [vary] during the burst.

3. (Amended). The method of claim 1 further comprising the step of applying the said at least one electrical burst in response to a detectable electrical activity of the brain. [wherein said burst is synchronized to detected electrical activity of the brain.]

4. (Amended). The method of claim [1] 3 wherein said detect[ed]able electrical activity is an epileptiform electrical activity.

5. (Amended). The method of claim [1] 3 wherein said detect[ed]able electrical activity predicts impending epileptiform electrical activity.

6. The method of claim 1 wherein said pulse parameters are selected from the group consisting of selected electrode, pulse width, pulse amplitude, pulse polarity, and pulse-to-pulse interval.

7. The method of claim 1 wherein said at least one pulse parameter is pulse-to-pulse interval.

8. The method of claim 7 wherein said pulse-to-pulse interval is between about 3 and 300 microseconds.

9. (Amended). The method of claim 7 further comprising the step of randomly varying [wherein] said pulse-to-pulse interval [is randomly varied] for at least a portion of the burst.

10. (Amended). The method of claim 7 further comprising the step of pseudo-randomly varying [wherein] said pulse-to-pulse interval [is pseudo-randomly varied] for at least a portion of the burst.

11. (Amended). The method of claim 7 further comprising the step of fractally varying [wherein] said pulse-to-pulse interval [is fractally varied] for at least a portion of the burst.

12. (Amended). The method of claim 7 further comprising the step of incrementally increasing [wherein] said pulse-to-pulse interval [is incrementally increased] for at least a portion of the burst.

13. (Amended). The method of claim 7 further comprising the step of incrementally decreasing [wherein] said pulse-to-pulse interval [is incrementally decreased] for at least a portion of the burst.

14. (Amended). The method of claim 7 further comprising the step of varying [wherein] said pulse-to-pulse interval [is varied effectively] to avoid initiation of epileptiform activity.

15. (Amended). The method of claim 7 further including the step of delivering a hyper-polarizing pulse to said brain tissue prior to initiating the application of said at least one electrical burst [pulse].

16. The method of claim 15 wherein said hyper-polarizing pulse is 40 to 500 microseconds in length.

17. The method of claim 15 wherein said hyper-polarizing pulse is comparatively lower in amplitude and longer in pulse length than pulses in said at least one electrical burst.

18. (Amended). The method of claim 3 [7] wherein said detectable electrical activity [signal] in the brain is epileptiform activity and said method further includes the step of detecting said electrical activity [signal] in the brain prior to initiating the application of said at least one electrical burst.

19. (Amended). The method of claim 18 wherein said at least one pulse parameter is related to said detect[ed]able electrical activity [signal] in the brain

20. (Amended). The method of claim 18 further including the step of determining [the] a pulse-to pulse interval of said electrical activity [signal] in the brain prior to initiating [the application of] said at least one electrical burst.

21. The method of claim 20 wherein said at least one pulse parameter is related to said detected epileptiform pulse-to-pulse interval in the brain.

22. (Amended). The method of claim 20 wherein the at least one pulse parameter is [said] pulse-to-pulse interval and further comprising the step of varying said pulse-to-pulse interval [is varied] in length to between about 10% and about 400% of said epileptiform pulse-to-pulse interval.

23. The method of claim 1 wherein said at least one pulse parameter is pulse amplitude.

24. (Amended). The method of claim 23 further comprising the step of randomly varying [wherein] said pulse amplitude [is randomly varied] for at least a portion of the burst.

25. (Amended). The method of claim 23 further comprising the step of pseudo-randomly varying [wherein] said pulse amplitude [is pseudo-randomly varied] for at least a portion of the burst.

26. (Amended). The method of claim 23 further comprising the step of fractally varying [wherein] said pulse amplitude [is fractally varied] for at least a portion of the burst.

27. (Amended). The method of claim 23 further comprising the step of incrementally increasing [wherein] said pulse amplitude [is incrementally increased] for at least a portion of the burst.

28. (Amended). The method of claim 23 further comprising the step of incrementally decreasing [wherein] said pulse amplitude [is incrementally decreased] for at least a portion of the burst.

29. (Amended). The method of claim 23 further including the step of delivering a hyper-polarizing pulse to said brain tissue prior to initiating the application of said at least one electrical burst [pulse].

30. The method of claim 29 wherein said hyper-polarizing pulse is 40 to 500 microseconds in length.

31. The method of claim 29 wherein said hyper-polarizing pulse is comparatively lower in amplitude and longer in pulse length than pulses in said at least one electrical burst.

32. The method of claim 1 wherein said at least one pulse parameter is pulse width.

33. (Amended). The method of claim 32 further comprising the step of randomly varying [wherein] said pulse width [is randomly varied] for at least a portion of the burst.

34. (Amended). The method of claim 32 further comprising the step of pseudo-randomly varying [wherein] said pulse width [is pseudo-randomly varied] for at least a portion of the burst.

35. (Amended). The method of claim 32 further comprising the step of fractally varying [wherein] said pulse width [is fractally varied] for at least a portion of the burst.

36. (Amended). The method of claim 32 further comprising the step of incrementally increasing [wherein] said pulse width [is incrementally increased] for at least a portion of the burst.

37. (Amended). The method of claim 32 further comprising the step of incrementally decreasing [wherein] said pulse width [is incrementally decreased] for at least a portion of the burst.

38. (Amended). The method of claim 32 further including the step of delivering a hyper-polarizing pulse to said brain tissue prior to initiating the application of said at least one electrical burst [pulse].

39. The method of claim 38 wherein said hyper-polarizing pulse is 40 to 5000 microseconds in length.

40. The method of claim 38 wherein said hyper-polarizing pulse is comparatively lower in amplitude and longer in pulse length than pulses in said at least one electrical burst.

41. (Amended). The method of claim 3 [1] wherein said detectable electrical activity [signal] in the brain is epileptiform activity and said method further includes the steps of:

detecting said electrical activity [signal] in the brain prior to initiating [the application of] said at least one electrical burst[,];

determining [the] both [the] an interval of said electrical activity [signal] in the brain prior to initiating [the application of] said at least one electrical burst and a characteristic of the electrical activity [signal,]; and

delaying the initiation of [the application of] said at least one electrical burst after the onset of the characteristic of the electrical activity [signal] for a period of time between 5% and about 100% of said interval of said electrical activity [signal].

42. (Amended). The method of claim 3 [1] wherein said detectable electrical activity [signal] is an epileptiform electrical activity, said method further comprising the steps of:

[again] detecting said electrical activity [signal] in the brain after the application of said at least one electrical burst; and

analyzing said electrical activity [signal] for epileptiform activity to produce a re-analyzed electrical activity.

43. (Amended). The method of claim 42 wherein said re-analyzed electrical activity [signal shows] comprises epileptiform electrical activity, said method comprising the further steps of:

[again] re-applying to said brain tissue at least one electrical burst comprising a multiplicity of pulses, said pulses having pulse parameters[,]; and

varying at least one of [which] the pulse parameters [vary] during the re-applied at least one electrical burst.

44. (Amended). The method of claim 43 wherein the at least one [or] pulse parameters varied in said re-applied at least one electrical burst are different than the pulse parameters varied in [said] an earlier at least one electrical burst.

45. The method of claim 44 wherein said steps are repeated up to ten times.

46. (Amended). [The] A method [of claim 1] for treating an abnormal neurological condition comprising the steps of:

applying to brain tissue, electrical bursts comprising a multiplicity of pulses independently to different electrodes spatially separated in [said] a brain, said pulses having pulse parameters and said application of electrical bursts being in response to a detectable electrical activity; and[,]

varying at least one of the [which] pulse parameters independently [varies] during the bursts.

47. (Amended). The method of claim 46 further comprising delivering [wherein] said multiplicity of pulses [are delivered] simultaneously to said electrodes.

48. (Amended). The method of claim 46 further comprising delivering [wherein] said multiplicity of pulses [delivered] to said electrodes, said electrodes being [are] configured to treat a multi-focal epilepsy.

49. (Amended). The method of claim 46 wherein said electrical activity [signal] is an epileptiform electrical activity and wherein said electrodes are located near an epileptigenic focus, said method further comprising applying comparatively lower amplitude pulses to electrodes spatially closer to the epileptigenic focus.

50. An implantable neurostimulator assembly for treating a disorder in a human brain, comprising in combination:

a.) at least a first electrical neurostimulator electrode, and

b.) at least a first electrical signal source connectable to said at least first electrical neurostimulator electrode, said first electrical signal source initiating a stimulation burst to said at least a first electrical neurostimulation electrode, said burst comprising pulses having pulse parameters, which pulse parameters vary during said burst.

51. (Amended). The implantable neurostimulator of claim 50 further comprising at least a first brain electrical activity sensor for sensing electrical activity in a [said] brain.

52. The implantable neurostimulator of claim 50 wherein said first electrical signal source is configured to vary pulse parameters selected from the group consisting of electrode choice, pulse width, pulse amplitude, pulse polarity, and applied pulse-to-pulse interval.

53. The implantable neurostimulator of claim 50 wherein said first electrical signal source is configured to vary said pulse parameters randomly, pseudo-randomly, fractally, incrementally increasing, incrementally decreasing, or effectively to avoid initiation of epileptiform activity.

54. (Amended). The implantable neurostimulator of claim 50 wherein said first electrical signal source is configured to deliver a hyper-polarizing pulse to [said] brain tissue prior to initiating the application of said at least one electrical burst.

55. The implantable neurostimulator of claim 54 wherein said hyper-polarizing pulse is 40 to 5000 microseconds in length.

56. The implantable neurostimulator of claim 54 wherein said hyper-polarizing pulse is comparatively lower in amplitude and longer in pulse length than pulses in said at least one electrical burst.

57. (Amended). The implantable neurostimulator of claim 51[0] wherein said at least a first brain electrical activity sensor is configured to detect epileptiform activity prior to initiating the application of said at least one electrical burst.

58. (Amended). The implantable neurostimulator of claim 51[0] wherein said at least a first brain electrical activity sensor is configured to determine the epileptiform pulse-to-pulse interval of said electrical activity [signal] in the brain prior to initiating the application of said at least one electrical burst.

59. The implantable neurostimulator of claim 58 wherein said first electrical signal source is configured to deliver an applied pulse-to-pulse interval that is varied in length between about 105% and about 400% of said epileptiform pulse-to-pulse interval.

60. (Amended). The implantable neurostimulator of claim 58 wherein said first electrical signal source is configured to again apply [to said brain tissue] at least one electrical burst comprising a multiplicity of pulses, said pulses having pulse parameters, at least one of which pulse parameters vary during the burst, when said at least a first brain electrical activity sensor detects epileptiform electrical activity after application of said first electrical burst.

61. The implantable neurostimulator of claim 58 wherein said first electrical signal source is configured to vary said one or pulse parameters in said re-applied at least one electrical burst that are different than the pulse parameters varied in said at least one electrical burst.

62. (Amended). The implantable neurostimulator of claim 51[0] wherein said first brain electrical activity sensor comprises multiple brain electrical activity sensors.

63. (Amended). The implantable neurostimulator of claim 62 wherein said multiple brain electrical activity sensors comprise[s] sensors for measuring said at least one brain electrical activity of said brain simultaneously at different sites in [said] a brain.

64. (Amended). The implantable neurostimulator of claim 62 wherein said sensors are configured to measure said brain activity at a depth within [the] a brain.

65. (Amended). The implantable neurostimulator of claim 62 wherein said sensors are configured to measure said brain activity on [the] a scalp.

66. (Amended). A method for treating an abnormal neurological condition comprising the steps of:

applying to brain tissue at least one electrical burst comprising a multiplicity of pulses[, said at least one electrical burst being synchronized]; and

synchronizing said at least one electrical burst to detectable[ed] electrical activity of the brain.

67. The method of claim 66 wherein said detected electrical activity is an epileptiform electrical activity.

68. The method of claim 66 wherein said detected electrical activity predicts impending epileptiform electrical activity.

69. (Amended). A method for treating an abnormal neurological condition comprising the steps of:

determining the interval of an electrical signal in a [the] brain; and

applying to brain tissue at least one electrical burst comprising a multiplicity of pulses, said pulses having pulse parameters related to said detected interval in the brain.

70. (Amended). The method of claim 69 wherein the determined [said detected] interval comprises epileptiform pulse-to-pulse intervals.

71. The method of claim 70 wherein said pulse-to-pulse interval is varied in length between about 10% and about 400% of said epileptiform pulse-to-pulse interval.

72. (Amended). A method for treating an abnormal neurological condition comprising the steps of:

detecting an electrical activity [signal] in a [the] brain prior to initiating the application of at least one electrical burst[,];

determining the interval of said electrical activity [signal] in the brain prior to initiating the application of said at least one electrical burst; and

delaying the initiation of the application of said at least one electrical burst after the onset of the detected electrical activity [signal] for a period of time between 5% and about 100% of said interval of said electrical activity [signal].

73. (Amended). The method of claim 72 wherein said electrical activity [signal] is an epileptiform electrical activity, said method further comprising the steps of again detecting said electrical activity [signal] in the brain after the application of said at least one electrical burst and analyzing said electrical activity [signal] for epileptiform activity.

74. (Amended). A method for treating an abnormal neurological condition comprising the steps of:

detecting electrical activity in a [the] brain; and

applying to brain tissue a multiplicity of pulses having pulse parameters independently to different electrodes spatially separated in said brain.

75. The method of claim 74 wherein said detected electrical activity is an epileptiform electrical activity.

76. The method of claim 74 wherein said detected electrical activity predicts impending epileptiform electrical activity.

77. (Amended). A method for treating an abnormal neurological condition comprising the steps of:

detecting electrical activity in a [the] brain; and

delivering a hyper-polarizing pulse to said brain [tissue] prior to initiating the application of at least one electrical pulse.

78. The method of claim 77 wherein said hyper-polarizing pulse is 40 to 5000 microseconds in length.

79. The method of claim 77 wherein said hyper-polarizing pulse is comparatively lower in amplitude and longer in pulse length than pulses in said at least one electrical burst.

80. The method of claim 77 further comprising the step of detecting epileptiform activity in said brain prior to initiating the application of said at least one electrical burst.

81. (Amended). The method of claim 80 further comprising the steps of determining epileptiform activity pulse-to-pulse interval and delivering [a t] at least one pulse having a pulse-to-pulse interval in length between about 105% and about 400% of said epileptiform activity pulse-to-pulse interval.